United States Senate
BUDGET COMMITTEE

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S.3 Biodefense Provisions

Summary

Last year, Congress passed and President George W. Bush signed into law the Project BioShield Act of 2003 (Public Law 108-276). Building on the BioShield Act, the S. 3 biodefense provisions take the necessary steps to better protect and strengthen our domestic public health infrastructure. Specifically, S.3 eliminates additional barriers to encourage the development of countermeasures needed to protect the nation against biological, radiological, or nuclear agents, as well as emerging infectious diseases. It expands the availability and accessibility of vaccines. Additionally, it strengthens capacity and coordination, so that we respond effectively in the event of a public health emergency.

Summary of Key Provisions

TITLE I – Biopreparedness Act of 2005

Subtitle A – Product Development

Chapter 1 – Partnering with the Private Sector

- Expands the definition of "qualified countermeasures" to include detection technologies and research tools.

- Encourages vaccine and countermeasure production by ensuring full patent restoration for the developed product.

- Improves efficiency during a public health emergency by allowing companies involved in the development of priority countermeasures to better coordinate the development, manufacture, distribution, purchase or sale of these countermeasures.

Chapter 2 -- Ensuring Regulatory Efficiency

- Establishes an expert commission to study laws and regulations applicable to countermeasures and vaccines that are in periodic short supply and make

recommendations to ensure the rapid availability of safe and effective products.

- Creates an FDA rapid-action team to work with the manufacturers who request assistance to identify and resolve problems by providing continuous, onsite assistance, in the event that such compliance issues could lead to a significant shortage of a vaccine or other biological product.
- Ensures fast track reviews for second generation vaccines and countermeasures.

- Provides for federal pre-emption of any State or local regulatory requirements that alter federal statutory or regulatory requirements for the safety, efficacy, labeling, or advertising of drugs and biological products if those requirements impede access to FDA-approved products.

Chapter 3 – Encouraging Vaccine and Countermeasure Production Capacity

- Encourages the construction and renovation of vaccine and countermeasure manufacturing facilities, as well as increased vaccine and countermeasure research and development, by offering new tax-based incentives and grants.

- Promotes a robust vaccine stockpile program and ensures the completion of future stockpile requests by permitting manufacturers to realize revenues for fulfilled stockpile orders.

Subtitle B – Litigation Reform

Chapter 1 – Protection for Countermeasures and Products Protecting Against Pandemics, Epidemics, and Bioterrorism

- Encourages the development of countermeasures and products protecting against pandemics, epidemics, and bioterrorism by extending federal protections to those who develop, distribute, prescribe, and administer these countermeasures during a public health emergency.

Chapter 2 – Vaccine Injury Compensation Program

- Requires the Secretary and the Attorney General of the United States to make recommendations to Congress regarding necessary modifications to federal programs and rules regarding litigation involving vaccines.

Subtitle C – Public Health Preparedness

Chapter 1 – Capacity to Respond

- Establishes the Pandemic Influenza Preparedness and Response Plan, which includes developing research to improve influenza vaccines, enhancing public awareness, and improving international and state surveillance capacity and the ability to direct vaccines and countermeasures to where they are most needed.

- Authorizes a real time electronic information technology structure for disease reporting to improve and enhance surveillance of infectious diseases and potential bioterror attacks and establishes a "Biointelligence Unit" at CDC to analyze the real time data.

- Permits the inspection, screening, and quarantining of live animals entering the United States for commercial or other purposes to protect domestic animal and human populations from diseases carried by imported live animals.

Chapter 2 – Public Health Workforce

- Expands the recruitment and retention of public health workers at the federal, state, and local levels by offering loan repayments in return for service in the FDA, NIH, CDC or other public health agency.

Chapter 3 – Preparedness Updates

- Requires the General Accounting Office to submit a report regarding biopreparedness to Congress no later than one year following enactment, including an assessment of state and local capacity to respond to bioterrorism and other public health emergencies.

- Highlights that in order to effectively combat bioterrorism and prevent the spread of deadly infectious disease, the United States should enhance cooperation and its activities globally.

Please note: S. 3 includes two additional titles not included in this summary